



[Billing Code 4140-01-P]

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

Submission for OMB review; 30-day Comment Request:

The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease  
Among Men and Women in Agriculture (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on April 23, 2013, Vol. 78, page 23942 and allowed 60-days for public comment. One public comment was received on April 23, 2013, that questioned spending taxpayer money for this research. An email response was sent on April 24, 2013, stating, “We received your comment. We will take your comments into consideration”. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s)

contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA\_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Jane Hoppin, Sc.D., Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, PO Box 12233, MD A3-05, Research Triangle Park, NC 27709, or call non-toll-free number 919-541-7622, or e-mail your request, including your address to: hoppin1@niehs.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture, 0925-0406 - REVISION- National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this information collection is to request initiation of a new dust specimen component as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA) as well as continue and complete phase IV

(2013-2015) of the Agricultural Health Study (AHS) and continue buccal cell collection. Phase IV will continue to update the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the AHS. The new BEEA dust component will include a brief paper-and-pen questionnaire mailed to the participant in advance of the home visit; at the home visit, the study phlebotomist will to collect and review the questionnaire, and collect the participant's disposable vacuum bag (or empty the dust from vacuums without disposable bags). The dust component will use similar procedures to ones that have been employed on other NCI studies to obtain information about the dust specimen and to collect and ship the dust specimen. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer. Phase IV questionnaire data are collected by using self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents are also asked to participate in the collection of biospecimens and environmental samples, including blood, urine, buccal cells (loose cells from the respondent's mouth), and vacuum dust. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among Agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 10,679.

### Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Reminder, Missing, and Damaged Scripts for Buccal Cell	Private and Commercial Applicators and Spouses	100	1	5/60	8
BEEA CATI Eligibility Script	Private Applicators	480	1	20/60	160
Mailed Consent, Pre-Visit Show Card, and Paper/Pen Dust Questionnaire	Private Applicators	160	1	20/60	53
BEEA Home Visit CAPI, Blood, Urine, & Dust x 1	Private Applicators	160	1	90/60	240
BEEA Schedule Home Visit Scripts	Private Applicators	20	3	5/60	5
BEEA Home Visit CAPI, Blood, & Urine x 3	Private Applicators	20	3	30/60	30
Paper/pen, CAWI or CATI	Private Applicators	13,855	1	25/60	5,773
Paper/pen, CAWI or CATI	Spouses	10,201	1	25/60	4,250
Paper/pen, CAWI or CATI	Proxy	635	1	15/60	159

July 10, 2013

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(Date)

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Rick Woychik,  
Deputy Director, NIEHS

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